Application No.: 10/615,716 40 Docket No.: 03818/100L650-US1

REMARKS

Applicants thank the Examiner for courtesies extended during a telephone call on August 19, 2004. The Examiner indicated to the Applicants representative that the Supplemental IDS filed May 10, 2004 was in fact considered in this case. The Examiner indicated that an initialed copy of the Supplemental IDS would be provided in the next action.

A second Supplemental IDS is also with this response. It contains several references cited in the European Search Report of a related case. The search report was mailed by the Office to the undersigned on August 26, 2004 and an IDS filed concurrently with this amendment is therefore timely.

I. Claim Status

Claims 1-54 are pending. Claims 3 and 4 have been cancelled without prejudice. Claims 2, 6, 8-47, 48-50 and 51 have been amended. Claim 1 has been amended to incorporate the definitions for M and S found in original claims 2 and 4. Claim 2 has been amended to incorporate the general Formula I from original claim 1 and the definitions for L and S from original claims 3 and 4. Claims 1 and 2 have further been amended to include pharmaceutically acceptable salts and solvates. Support for this amendment comes from the specification as filed at page 1 lines 7-8, page 16 lines 31-34 and page 17 lines 1-2. Claim 6 has been amended to correct an obvious typographical error. Claims 8-47 have been amended to add the phrase "and pharmaceutically acceptable salts thereof." Support for this amendment can be found in the specification as filed at page 1 lines 7-8, page 16 lines 31-34 and page 17 lines 1-2. Claim 48 has been amended to now recite the definitions for M and S found in original claims 2 and 4. Claims 49 and 50 have been amended to correct a now incorrect dependency. Claim 51 has been amended to now refer to method using a compound according to claim 2 instead of a compound according to Formula I. No new matter has been added by these amendments.

Docket No.: 03818/100L650-US1

II. Claim Rejections

a) 35 U.S.C. §112 First Paragraph

Claims 1-7 and 48-54 stand rejected under 35 USC §112 first paragraph. The Examiner contends that while being enabled for a compound where M is a macrolide of Formula II, L is a group of Formula VA or VB and S is a group of formula X the specification does not reasonably provide enablement for M being a macrolide, S being any steroidal anti-inflammatory subunit and L being any linker.

Without conceding that the Examiners position was correct claim 1 has been amended to now recite the definitions for M and S originally found in claims 2 and 4. Applicants submit that the recitation of M and S as presented in original claims 2 and 4 and L as originally filed in claim 1 are fully enabled. Applicants submit that many examples of linker molecules are given in the specification and genus of claim 2 and the construction of the present conjugates using these linkers has been generally described and exemplified. (see pages 23-32) Applicants submit that based on this extensive teaching of the present specification a person of ordinary skill can readily select any number of appropriate linker molecules. Accordingly, the breadth of claim 1 is amply enabled by the specification. The specification describes numerous linker moieties which fall under the generic scope of amended claim 1. Claim 2 has been amended to now recite in addition to the definition of M as a macrolide of Formula II the definitions for L being a group of Formula VA and VB originally found in claim 3 and S being a group of formula X originally found in claim 4. Claims 5-7 have been amended to now depend from amended claim 2. Claim 48 has been amended to recite a process for the preparation of compounds within amended claim 1. Applicants respectfully request reconsideration and withdrawal of this rejection.

b) 35 U.S.C. §112 Second Paragraph Rejections

Claims 8-47 stand rejected under 35 U.S.C. §112 second paragraph for failing to end in a period.

Claims 8-47 have been amended to now include a period. Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 48 has been rejected under 35 U.S.C. §112 second paragraph for failing to recite definitions for the M, L and S groups. Claim 48 has been amended to now recite definitions for the M, L and S groups. Applicants respectfully request reconsideration and withdrawal of this rejection.

Non-statutory Double Patenting Rejection

Claims 1-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 10/616,046. The Examiner contends that although the conflicting claims are not identical they are not patentably distinct from each other because the compounds of the instant application are encompassed by the compounds of the copending application. Without conceding the Examiners position, concurrent with the filing of this amendment applicants also file a terminal disclaimer in compliance with 37 CFR 1.32(c).

c) 35 U.S.C. §102(b) Rejection

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by WO 97/41255. Claim 1 has been amended to incorporate the limitations found in original claims 1 and 4. Amended claim 1 therefore cannot be anticipated by WO 97/41255. Applicants respectfully request removal of this rejection.

Application No.: 10/615,716 43 Docket No.: 03818/100L650-US1

Conclusion

It is believed that the application is now in condition for allowance. Favorable action is earnestly solicited. If the Examiner believes a telephonic interview would expedite the prosecution of the instant case, she is invited to call the applicants representative whose contact information appears below.

Dated: November 11, 2004

Respectfully submitted,

Nicholas Sisti, Ph.D, J.D.

Registration No.: 54,453

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorneys/Agents For Applicant